K112050 NOV 18 2011 1/6

15 510(K) SUMMARY

SPONSOR'S NAME & ADDRESS

Biosense Webster, Inc.
3333 Diamond Canyon Road
Diamond Bar, CA 91765

OFFICIAL CORRESPONDENT

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SUBMISSION DATE

July 13, 2011

TRADE NAME

SOUNDSTAR® *eco* DIAGNOSTIC ULTRASOUND CATHETER

(Part Number: M-5723-15 / Catalogue Number: 10438577, Compatible with Siemens Ultrasound systems)

SOUNDSTAR® *eco* DIAGNOSTIC ULTRASOUND CATHETER

(Part Number: M-5723-16 / Catalogue Number: 10439072, Compatible with GE Ultrasound systems)

COMMON NAME

Electrophysiology Mapping/Ultrasound Catheter

CLASSIFICATION NAME/PRODUCT CODE

Intravascular Ultrasound Catheter/OBJ

CLASSIFICATION

Class II, 21 CFR 870.1200

PREDICATE DEVICE

The modified SOUNDSTAR *eco*10F and SOUNDSTAR *eco*10FG Catheters are substantially equivalent to the Biosense Webster SOUNDSTAR 3D Ultrasound Catheter (SNDSTR10) cleared on May 15, 2007 via 510(k) K070242 and also SOUNDSTAR 3D Ultrasound Catheter (SNDSTR10G) cleared on August 7, 2009 via 510(k) K092064 respectively.

DESCRIPTION OF MODIFIED DEVICE

The modified SOUNDSTAR *eco*10F and SOUNDSTAR *eco*10FG Catheters are both 90 cm 10F IntraCardiac Echo (ICE) Catheters with an acoustic array identical to the currently cleared SNDSTR10 and SNDSTR10G Catheters. The catheters have a magnetic location sensor (providing location information to the CARTO 3 Navigation System Version 2.2) and an ultrasound transducer (acquiring real time ultrasound images) embedded in the tip.

The modified SOUNDSTAR *eco* Catheters have a bifurcated 'tail' originating from their handle which is nearly identical to the bifurcated tail of the predicate devices. One leg terminates in the SOUNDSTAR Flex Tab connector, which connects via the appropriate SwiftLink cable to the corresponding Ultrasound system. For the SOUNDSTAR *eco*10F Catheter the SwiftLink cable connects to Acuson Cypress, Acuson Sequoia or Acuson X300 Ultrasound systems. For the SOUNDSTAR *eco*10FG Catheter the SwifLink cable connects to GE Vivid-i or Vivid-q Ultrasound systems.

Both versions of SOUNDSTAR *eco*10F and SOUNDSTAR *eco*10FG Catheters are based on the existing SOUNDSTAR 3D 10F (SNDSTR10) and SOUNDSTAR 3D 10FG (SNDSTR10G) catheters and have the same intended use and clinical applications. The predicate and modified catheters share the majority of components and manufacturing process as explained previously.

The modified SOUNDSTAR *eco*10F and SOUNDSTAR *eco*10FG Catheters, when connected to the corresponding Ultrasound Systems, will provide real-time integration of ultrasound images with CARTO 3 Version 2.2 electromagnetic acquired maps.

INDICATIONS FOR USE

The Biosense Webster SOUNDSTAR® *eco* Diagnostic Ultrasound Catheter and related accessory devices are indicated for intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart. When used with compatible CARTO® 3 EP Navigation Systems, the SOUNDSTAR® *eco* Catheter provides location information. Please refer to the Compatibility Matrix Insert for Compatible CARTO® 3 Systems as each catheter is compatible with a specific version of CARTO® 3 and is not backwards compatible with previous versions of CARTO® 3 EP Navigation Systems.

DESCRIPTION OF MODIFICATION

The modified SOUNDSTAR *eco*10F and SOUNDSTAR *eco*10FG Catheters are identical to the currently cleared SNDSTR10F and SNDSTR10FG Catheters in terms of: Indication for Use, Material, Manufacturing methods, Operating principles, Fundamental Scientific Technology, Performance, Array and Sensor specifications, Shelf Life and Sterilization methods. Modifications were only made in the handle of the catheter. Specifically, the catheter specific electronics (i.e. memory for sensor calibration data) were moved to the Hypertonics connector, and non catheter specific electronics (i.e. amplifiers) were moved to the Extension Cable.

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SOUNDSTAR® eco ULTRASOUND CATHETER COMPATIBILITY MATRIX INSERT

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For catheter M-5723-15
eco 10F

SOUNDSTAR® eco DIAGNOSTIC ULTRASOUND CATHETER COMPATIBILITY MATRIX INSERT

ADDENDUM TO SOUNDSTAR® eco DIAGNOSTIC ULTRASOUND CATHETER INSTRUCTIONS FOR USE (M-5276-701)

The SOUNDSTAR® eco Diagnostic Ultrasound Catheter has been validated for use with the Siemens ultrasound systems in conjunction with the CARTO® EP Navigation Systems listed in the following table.

Ultrasound Systems	CARTO® Systems
ACUSON Sequoia™	CARTO® 3 version 2.2 *
ACUSON Cypress™	CARTO® 3 version 2.2 *
ACUSON X300™	CARTO® 3 version 2.2 *

*The SOUNDSTAR® eco DIAGNOSTIC ULTRASOUND CATHETER is not backwards compatible with previous versions of CARTO® 3 EP Navigation System.

TRANSDUCER SURFACE TEMPERATURE

The following table provides the maximum surface temperature of the SOUNDSTAR® Catheter with the relevant ultrasound system. The tissue mimicking material (TMM) temperature is displayed in accordance with IEC 60601-2-37 requirements.

Ultrasound System	TMM (Max Temp)
ACUSON Sequoia*	42.1°C
ACUSON Cypress*	42.1°C
ACUSON X300*	41.8°C

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SOUNDSTAR® *eco*
ULTRASOUND CATHETER
COMPATIBILITY MATRIX
INSERT

6/6

For catheter M5723-46
eco 10FG

SOUNDSTAR® eco DIAGNOSTIC ULTRASOUND CATHETER COMPATIBILITY MATRIX INSERT

ADDENDUM TO SOUNDSTAR® eco DIAGNOSTIC ULTRASOUND CATHETER INSTRUCTIONS FOR USE (M-5276-703)

The SOUNDSTAR® eco Diagnostic Ultrasound Catheter has been validated for use with the GE ultrasound systems in conjunction with the CARTO® EP Navigation Systems listed in the following table.

Ultrasound Systems	CARTO® Systems
Vivid-I*	CARTO® 3 version 2.2 *
Vivid-q*	CARTO® 3 version 2.2 *

*The SOUNDSTAR® eco DIAGNOSTIC ULTRASOUND CATHETER is not backwards compatible with previous versions of CARTO® 3 EP Navigation System.

TRANSDUCER SURFACE TEMPERATURE

The following table provides the maximum surface temperature of the SOUNDSTAR® Catheter with the relevant ultrasound system. The tissue mimicking material (TMM) temperature is displayed in accordance with IEC 60601-2-37 requirements.

Ultrasound System	TMM (Max Temp)
Vivid-I*	41.8°C
Vivid-q*	41.8°C

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

NOV 18 2011

Biosense Webster, Inc.
c/o Marina Guevrekian, Ph.D.
Senior Specialist, Regulatory Affairs
3333 Diamond Canyon Road
Diamond Bar, CA 91765

Re: K112050
Trade/Device Name: SOUNDSTAR® eco 10F and SOUNDSTAR® eco 10FG catheters
Regulatory Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II (Two)
Product Code: OBJ
Dated: October 20, 2011
Received: October 21, 2011

Dear Dr. Guevrekian:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

7 INDICATIONS FOR USE

510(k) No (if known): K112050

Device Name:
SOUNDSTAR® *eco* 10F CATHETER
SOUNDSTAR® *eco* 10FG CATHETER

Indications for Use:
The Biosense Webster SOUNDSTAR® *eco* Diagnostic Ultrasound Catheter and related accessory devices are indicated for intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart. When used with compatible CARTO® 3 EP Navigation Systems, the SOUNDSTAR® *eco* Catheter provides location information. Please refer to the Compatibility Matrix Insert for Compatible CARTO® 3 Systems as each catheter is compatible with a specific version of CARTO® 3 and is not backwards compatible with previous versions of CARTO® 3 EP Navigation Systems.

Prescription Use (Part 21 CFR 801 Subpart D) ___√___ AND/OR Over-The-Counter Use (21 CFR 801 Subpart C) _____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K112050

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SOUNDSTAR® *eco*
ULTRASOUND CATHETER
COMPATIBILITY MATRIX
INSERT

3/5

for catheter M-5723-15
eco 10F

SOUNDSTAR® eco DIAGNOSTIC ULTRASOUND CATHETER COMPATIBILITY MATRIX INSERT

ADDENDUM TO SOUNDSTAR® eco DIAGNOSTIC ULTRASOUND CATHETER INSTRUCTIONS FOR USE (M-5276-701)

The SOUNDSTAR® eco Diagnostic Ultrasound Catheter has been validated for use with the Siemens ultrasound systems in conjunction with the CARTO® EP Navigation Systems listed in the following table.

Ultrasound Systems	CARTO® Systems
ACUSON Sequoia™	CARTO® 3 version 2.2 *
ACUSON Cypress™	CARTO® 3 version 2.2 *
ACUSON X300™	CARTO® 3 version 2.2 *

*The SOUNDSTAR® eco DIAGNOSTIC ULTRASOUND CATHETER is not backwards compatible with previous versions of CARTO® 3 EP Navigation System.

TRANSDUCER SURFACE TEMPERATURE

The following table provides the maximum surface temperature of the SOUNDSTAR® Catheter with the relevant ultrasound system. The tissue mimicking material (TMM) temperature is displayed in accordance with IEC 60601-2-37 requirements.

Ultrasound System	TMM (Max Temp)
ACUSON Sequoia*	42.1°C
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SOUNDSTAR® eco ULTRASOUND CATHETER COMPATIBILITY MATRIX INSERT

SOUNDSTAR® eco DIAGNOSTIC ULTRASOUND CATHETER COMPATIBILITY MATRIX INSERT

ADDENDUM TO SOUNDSTAR® eco DIAGNOSTIC ULTRASOUND CATHETER INSTRUCTIONS FOR USE (M-5276-703)

For catheter M5723-16
eco 10F6

The SOUNDSTAR® eco Diagnostic Ultrasound Catheter has been validated for use with the GE ultrasound systems in conjunction with the CARTO® EP Navigation Systems listed in the following table.

Ultrasound Systems	CARTO® Systems
Vivid-i*	CARTO® 3 version 2.2 *
Vivid-q*	CARTO® 3 version 2.2 *

*The SOUNDSTAR® eco DIAGNOSTIC ULTRASOUND CATHETER is not backwards compatible with previous versions of CARTO® 3 EP Navigation System.

TRANSDUCER SURFACE TEMPERATURE

The following table provides the maximum surface temperature of the SOUNDSTAR® Catheter with the relevant ultrasound system. The tissue mimicking material (TMM) temperature is displayed in accordance with IEC 60601-2-37 requirements.

Ultrasound System	TMM (Max Temp)
Vivid-i*	41.8°C
Vivid-q*	41.8°C

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